

REMARKS

Claims 1-21 are pending in the Application. Claims 9-17 and 20-21 are withdrawn from consideration.

Claims 3 and 4 are objected to. Claims 3, 4, 18 and 19 are rejected under 35 U.S.C. §112, second paragraph. Claims 1, 3 and 6 are rejected under 35 U.S.C. §102(e). Claims 2, 5, 7 and 8 are rejected under 35 U.S.C. §103(a). Claims 4, 18 and 19 contain allowable subject matter.

Applicant addresses these objections and rejections below.

I. OBJECTIONS TO THE CLAIMS:

The Examiner has objected to claims 3 and 4 for not inserting a comma following the term "polymers." Office Action (9/8/2009), page 2. As indicated above, Applicant amended claims 3 and 4 to include a comma following the term "polymers." As a result, Applicant kindly requests the Examiner to withdraw the objections to the claims.

Claims 3 and 4 were not amended to overcome prior art but to correct typographical mistakes. Hence, no prosecution history estoppel arises from the amendments to claims 3 and 4. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 U.S.P.Q.2d 1705, 1711-12 (2002); 56 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2000). Further, the amendments made to claims 3 and 4 were not made for a substantial reason related to patentability and therefore no prosecution history estoppel arises from such amendments. See *Festo Corp.*, 62 U.S.P.Q.2d 1705 at 1707 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 41 U.S.P.Q.2d 1865, 1873 (1997).

II. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH:

The Examiner has rejected claims 3, 4, 18 and 19 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Office Action (9/8/2009), page 2. In particular, the Examiner asserts that there is insufficient

antecedent basis for the limitation of "filaments of the mesh section" in claims 3 and 4. *Id.* Applicant respectfully traverses.

Applicant kindly points out that there is not a "the" or a "said" prior to the term "filaments" in claims 3 and 4. Hence, the term "filaments" is not referring to a prior usage of the term "filaments" and thus does not have an antecedent basis problem. Furthermore, the phrase "the mesh section" in the phrase "filaments of the mesh section" refers to the prior usage of the mesh section in independent claim 1. Hence, the phrase "the mesh section" does not have an antecedent basis problem. Accordingly, the phrase "filaments of the mesh section" does not have an antecedent basis problem as alleged by the Examiner.

Furthermore, the Examiner asserts that the phrase "the curved tip" on line 19 of claim 18 lacks sufficient antecedent basis. Office Action (9/8/2009), page 2. Applicant respectfully traverses. This usage of the phrase "the curved tip" refers to the prior usage of the phrase "a curved tip" as stated in step (c) of claim 18.

Additionally, the Examiner asserts that the phrase "the distal end" on lines 23 and 26 of claim 18 lacks sufficient antecedent basis. Office Action (9/8/2009), page 2. Applicant respectfully traverses. These usages of the phrase "the distal end" refer to the prior usage of the phrase "a distal end" as stated in step (b) of claim 18.

As a result of the above, claims 3, 4, 18 and 19 particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The limitations of claims 3, 4 and 18 discussed above do not lack sufficient antecedent basis. Accordingly, Applicant kindly requests the Examiner to withdraw the rejections of claims 3, 4, 18 and 19 under 35 U.S.C. §112, second paragraph.

III. REJECTIONS UNDER 35 U.S.C. §102(e):

The Examiner has rejected claims 1, 3 and 6 under 35 U.S.C. §102(e) as being anticipated by Staskin et al. (U.S. Patent Application Publication No. 2003/0045774) (hereinafter "Staskin"). Applicant respectfully traverses these rejections for at least the reasons provided below and respectfully requests the Examiner to reconsider and withdraw these rejections.

For a claim to be anticipated under 35 U.S.C. §102, each and every claim limitation must be found within the cited prior art reference and arranged as required by the claim. M.P.E.P. §2131.

Applicant respectfully asserts that Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1. The Examiner cites paragraph [0118] of Staskin as disclosing the above-cited claim limitation. Office Action (3/4/2008), page 3; Office Action (9/8/2009), page 3. Applicant respectfully traverses.

Staskin instead discloses a sling that is "preferably rectangular for treating SUI in females" (Staskin, paragraph [0119], Fig. 4). This type of sling is commonly referred to as a "tape" sling. As discussed in the disclosure of the present application, such a design "do[es] not restore the normal anatomical relationship of the urinary bladder to the urethra." (Page 9, lines 9–10). By contrast, a contoured sling as claimed "is shaped to restore the normal anatomy of the urethra and base of the bladder," which encourages normal voiding following incontinence surgery. (Page 9, lines 10–13). Further, in the present invention, the normal anatomical position is restored not only of the urethra, but also of the base of the bladder.

There is no language in Staskin that discloses a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. Nor does Staskin disclose the desirability or importance of restoring the normal anatomical relationship of the urinary bladder to the urethra. Therefore, "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1, is not comparable to simply "a sling capable of being applied to an area beneath and supporting the urethra or bladder neck" as suggested by the Examiner (see page 3 of the Office Action dated 3/4/2008 and page 3 of the Office Action dated 9/8/2009)).

Thus, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131.

In response to Applicant's above arguments, the Examiner asserts that the sling of Staskin has dimensions comparable to the instant application. Office Action

(3/4/2008), page 9. Applicant respectfully disagrees. Staskin discloses that the sling 42 has a length X, width Y and thickness of approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.5808 mm to 0.711 mm, respectively. [0118]. However, Applicant discloses that Applicant's sling 3 is comprised of a generally central segment 5 and distal segments 7 and 8. Page 17, lines 9-10 of Applicant's Specification. The central segment of the tubular mesh sling 3 is approximately 2.5 cm wide and 4.0 cm long with a rapid taper over approximately 1.5 cm down to a size of 1.0 cm in width at distal ends 7 and 8. Page 17, lines 10-12 of Applicant's Specification. Thus, the sling of Staskin does not include comparable dimensions of the sling of the instant application and there is a structural difference between the claimed invention and the invention of Staskin. Hence, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131.

In further response to Applicant's above arguments, the Examiner states:

Staskin teaches that the sling is of sufficient dimensions to support the urethra and bladder [0026] and [0116], and furthermore provides that the sling is of comparable dimensions of the instant application as indicated by its anticipation of claim 3, regarding the dimensions of the sling. Office Action (9/8/2009), page 9.

Applicant respectfully traverses. Paragraphs [0026 and 0116] of Staskin do not teach that the sling is of sufficient dimensions to support the urethra and bladder as asserted by the Examiner. Staskin discloses a surgical mesh having a length sufficient to extend from a pubic space of the patient beneath the urethra to an abdomen of the patient on either side of a bladder of the patient; a dilator for passage through tissue of the patient, the dilator being operatively associated with the surgical mesh; and the dilator including surfaces that are sized and shaped to atraumatically deflect tissue during passage of the dilator through tissue. [0026]. Staskin additionally discloses that the sling 42 has a length X, width Y and thickness of approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.5808 mm to 0.711 mm, respectively. [0118].

Hence, Staskin discloses a mesh having a length sufficient to extend from a pubic space of the patient beneath the urethra to an abdomen of the patient on either side of a bladder of the patient. Further, Staskin discloses a sling with a length X, width Y and thickness of approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.5808 mm to 0.711 mm, respectively.

There is no language in the cited passages that discloses a sling that is of sufficient dimensions to support the urethra and bladder. Staskin only discloses that the mesh has a length sufficient to extend from a pubic space of the patient beneath the urethra to an abdomen of the patient on either side of a bladder of the patient.

Neither is there any language in the cited passages that asserts that the tape sling of Staskin is shaped to fit and support the urethra and bladder as asserted by the Examiner. Office Action (9/8/2009), page 9. Again, Staskin only discloses that the mesh has a length sufficient to extend from a pubic space of the patient beneath the urethra to an abdomen of the patient on either side of a bladder of the patient. There is no language in the cited passages that discloses that the tape sling of Staskin is shaped to fit and support the urethra and bladder or that the tape sling can be shaped as a "sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder."

Furthermore, the Examiner asserts that paragraphs [0118 and 0119] of Staskin discloses that the tape sling of Staskin is capable of being contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. Office Action (9/8/2009), page 9. Applicant respectfully traverses.

As stated above, Staskin discloses that the sling 42 has a length X, width Y and thickness of approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.5808 mm to 0.711 mm, respectively. [0118]. However, Applicant discloses that Applicant's sling 3 is comprised of a generally central segment 5 and distal segments 7 and 8. Page 17, lines 9-10 of Applicant's Specification. The central segment of the tubular mesh sling 3 is approximately 2.5 cm wide and 4.0 cm long with a rapid taper over approximately 1.5 cm down to a size of 1.0 cm in width at distal ends 7 and 8. Page 17, lines 10-12 of Applicant's Specification. Thus, the sling

of Staskin does not include comparable dimensions of the sling of the instant application and there is a structural difference between the claimed invention and the invention of Staskin. Hence, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131.

Applicant further asserts that Staskin does not disclose "said instrument defining in part a progressively curved shaft portion positioned between distal and proximal ends with an attached insertion handle located at its proximal end" as recited in claim 1. The Examiner cites shaft portion 60 of Staskin as disclosing the claimed shaft portion. Office Action (3/4/2008), page 3; Office Action (9/8/2009), page 3. Applicant respectfully traverses the assertion that Staskin discloses the above-cited claim limitation.

Staskin instead discloses that the radius of the curvature of the needle 60 is substantially constant. [0179]. Hence, the curvature of the needle 60 of Staskin is substantially constant. It is not progressively curved as required by claim 1. Thus, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131.

In response to Applicant's above arguments, the Examiner cites paragraph [0015] and Figure 4 of Staskin as allegedly disclosing that needle 60 of Staskin is progressively curved. Office Action (9/8/2009), page 9. Applicant respectfully traverses.

Staskin discloses that need 60 is arc-shaped as illustrated in Figure 4. An arc-shaped needle has a curvature that is substantially constant as illustrated in Figure 4 of Staskin. It is not progressively curved as required by claim 1. Thus, Staskin does not disclose all of the limitations of claim 1, and thus Staskin does not anticipate claim 1. M.P.E.P. §2131.

Claims 3 and 6 each recite combinations of features of independent claim 1, and hence claims 3 and 6 are not anticipated by Staskin for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

Claims 3 and 6 recite additional features, which, in combination with the features of the claims upon which they depend, are not anticipated by Staskin.

For example, Staskin does not disclose "wherein the progressively curved shaft portion has a diameter of approximately 3.5 millimeters (mm) to 4.0 mm and a progressive curve with a maximum radius of approximately 5.1 cm" as recited in claim 6. The Examiner cites needle 60 of Staskin as disclosing the claimed shaft portion. Office Action (3/4/2008), page 3; Office Action (9/8/2009), page 4. Appellant traverses the assertion that Staskin discloses the above-cited claim limitation.

Staskin instead discloses that the length N of the needle 60 is approximately within the range of 16.5 cm to 24.1 cm (6.5 inches to 9.5 inches) and has a preferred external diameter of approximately 3.175 mm (0.125 inch). [0177]. Staskin further discloses that the radius of the curvature of the needle 60 is substantially constant. [0179].

There is no language in Staskin that discloses that needle 60 of Staskin (Examiner asserts that needle 60 of Staskin discloses the claimed curved shaft portion) has a diameter of approximately 3.5 mm to 4.0 mm. Instead, Staskin discloses that needle 60 of Staskin has an external diameter of approximately 3.175 mm. Further, there is no language in Staskin that discloses that needle 60 of Staskin (Examiner asserts that needle 60 of Staskin discloses the claimed curved shaft portion) has a progressive curve with a maximum radius of approximately 5.1 cm. As discussed above, Staskin instead discloses that needle 60 of Staskin has an external diameter of approximately 3.175 mm. Further, the curvature of the needle 60 is substantially constant. It is not progressively curved. And it does not have a progressive curve with a maximum radius of approximately 5.1 cm.

Thus, Staskin does not disclose all of the limitations of claim 6, and thus Staskin does not anticipate claim 6. M.P.E.P. §2131.

In response to Applicant's above arguments, the Examiner asserts that the needle 60 of Staskin having an external diameter of approximately 3.175 mm corresponds to the claim limitation of a curved shaft portion that has a diameter of

approximately 3.5 millimeters (mm) to 4.0 mm. Office Action (9/8/2009), page 10. Applicant respectfully traverses.

A diameter of 3.175 mm does not correspond to a diameter of approximately 3.5 mm to 4.0 mm. A person skilled in the art would not make such an interpretation. How can 3.175 mm be approximately 3.5 mm to 4.0 mm? The Examiner must provide a basis in fact and/or technical reasoning to support the assertion that a diameter of 3.175 mm corresponds to a diameter of approximately 3.5 mm to 4.0 mm. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). That is, the Examiner must provide extrinsic evidence that must make clear that a diameter of 3.175 mm corresponds to a diameter of approximately 3.5 mm to 4.0 mm, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented a *prima facie* case of anticipation for rejecting claim 6. M.P.E.P. §2112.

As a result of the foregoing, Applicant respectfully asserts that not each and every claim limitation was found within Staskin, and thus claims 1, 3 and 6 are not anticipated by Staskin. M.P.E.P. §2131.

IV. REJECTIONS UNDER 35 U.S.C. §103(a):

The Examiner has rejected claims 2 and 8 under 35 U.S.C. §103(a) as being unpatentable over Staskin in view of Inman et al. (U.S. Patent Application Publication No. 2003/0065246) (hereinafter "Inman"). The Examiner has further rejected claims 5 and 7 under 35 U.S.C. §103(a) as being unpatentable over Staskin. Applicant respectfully traverses these rejections for at least the reasons stated below and respectfully requests the Examiner to reconsider and withdraw these rejections.

- A. Claims 2 and 8 are not properly rejected under 35 U.S.C. §103(a) as being unpatentable over Staskin in view of Inman.
1. Claims 2 and 8 are patentable over Staskin in view of Inman for at least the reasons that claim 1 is not anticipated by Staskin.

Claims 2 and 8 recite the combinations of features of independent claim 1, and hence claims 2 and 8 are patentable over Staskin in view of Inman for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

2. Claim 2 is patentable over Staskin in view of Inman.

Applicant respectfully asserts that Staskin and Inman, taken singly or in combination, do not teach "wherein the insertion handle further comprises a digit control accommodation, said digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth" as recited in claim 2. The Examiner cites paragraphs [0046, 0051 and 0053] of Inman as teaching the above-cited claim limitations. Office Action (3/4/2008), page 6; Office Action (9/8/2009), page 5. Applicant respectfully traverses.

Inman instead teaches that the handle 12 has a major anterior surface 64 that is best seen in Figure 4. [0046]. Inman further teaches that the height H of the handle 12 is preferably between about 3.25 inches and about 4.75 inches. [0046]. Furthermore, Inman teaches that the handle 12 has a longitudinal axis A along its height H, where the handle 12 preferably includes an elongate channel 32 extending across the width W of the handle 12. [0051]. Additionally, Inman teaches that the channel 32 has an axis that extends substantially perpendicular to the longitudinal axis A of the handle 12. [0051]. Further, Inman teaches that the height (length) of the channel 32 along the longitudinal axis A of the handle 12 is more than 0.5 inches and less than 1 inch, more preferably the length is about 0.9 inches and that the depth of the channel 32 is preferably between 25% and 100% of the depth of the handle 12. [0051]. In addition, Inman teaches that the height H to width W ratio of the handle 12 is preferably greater than 3:1, and the depth D to width W ratio is preferably less than 1:2. [0053].

Hence, Inman teaches that handle 12 preferably includes an elongate channel 32 extending across the width W of the handle 12, where the height (length) of the channel 32 along the longitudinal axis A of the handle 12 is more than 0.5 inches and less than 1 inch, more preferably the length is about 0.9 inches and that the depth of

the channel 32 is preferably between 25% and 100% of the depth of the handle 12. Inman further teaches that the height H to width W ratio of the handle 12 is preferably greater than 3:1, and the depth D to width W ratio is preferably less than 1:2.

There is no language in the cited passages that teaches an insertion handle that comprises a digit control accommodation. If the Examiner is asserting that channel 32 of Inman corresponds to the claimed digit control accommodation, Applicant respectfully requests the Examiner to provide a basis in fact and/or technical reasoning to support such an assertion. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). That is, the Examiner must provide extrinsic evidence that must make clear that channel 32 of Inman corresponds to the claimed digit control accommodation, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. M.P.E.P. §2112.

Further, there is no language in the cited passages that teaches a digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth. Instead, Inman teaches that the length of channel 32 is between 0.5 inches (1.3 cm) and 1.0 inches (2.5 cm). See http://manuelsweb.com/in_cm.htm. Further, Inman teaches that the H to width W ratio of the handle 12 is preferably greater than 3:1, hence, one may assume that the width of channel 32 to be between .43 cm and .83 cm.

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 2, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

In response to Applicant's above arguments, the Examiner again asserts that channel 32 of Inman is interpreted as a digit control accommodation. Office Action (9/8/2009), page 10. The Examiner further states that channel 32 of Inman provides a surface on the handle which may be used to control movement of the handle by the surgeon. *Id.* at page 11.

Inman does teach that the anterior surface 64 preferably has a plurality of tactile surfaces 22, 24, 26 and 28 extending in a direction substantially perpendicular to the longitudinal axis. [0054]. However, there is no language in Inman that tactile surfaces 22, 24, 26 and 28 are used to control movement of the handle.

Furthermore, in response to Applicant's above arguments, the Examiner cites Staskin as teaching a length of 2.54 cm, a width of 2.8 to 4 cm, and a depth of 1.4 to 2 cm. Office Action (9/8/2009), page 11. Applicant notes that the Examiner has not cited to any passage in Staskin in support of the Examiner's assertion. Applicant has thoroughly reviewed Staskin and could not identify any language to support the Examiner's assertion. Applicant kindly requests the Examiner to specifically cite the passage(s) in Staskin that supports the Examiner's contention pursuant to 37 C.F.R. §1.104(c)(2). Furthermore, Applicant could not locate any language in Staskin that discusses the dimensions in connection with a digit control accommodation. Applicant kindly requests the Examiner to particularly point out in Staskin where Staskin teaches the dimensions of a digit control accommodation pursuant to 37 C.F.R. §1.104(c)(2).

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 2, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

3. Examiner's reasoning for modifying Staskin with Inman to include the missing claim limitation of claim 2 is insufficient to establish a *prima facie* case of obviousness.

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Therefore, an Examiner may often find every element of a claimed invention in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See Id.* In order to establish a *prima facie* case of obviousness, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of

the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). The Examiner must provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited approvingly in *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007)).

As understood by Applicant, the Examiner admits that Staskin does not teach "wherein the insertion handle further comprises a digit control accommodation, said digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth" as recited in claim 2. Office Action (3/4/2008), page 6; Office Action (9/8/2009), page 4. The Examiner asserts that Inman teaches the above-cited claim limitation. *Id.* The Examiner's reasoning for modifying Staskin with Inman to include the above-cited claim limitation is "in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure." Office Action (3/4/2008), page 6; Office Action (9/8/2009), page 5. The Examiner's reasoning is insufficient to establish a *prima facie* case of obviousness in rejecting claim 2.

The Examiner has not provided any rational underpinning as to how the Examiner derived her motivation for modifying Staskin to include the above-cited missing claim limitation. The Examiner simply states "in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure" as reasoning for modifying Staskin to include the above-cited claim limitation. While the Examiner may consider many factors in finding a reason to combine, the Examiner still must explain how the Examiner derived the reasoning for modifying Staskin to include the above-cited missing claim limitation. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007). The Examiner appears to be relying upon her own subjective opinion which is insufficient to support a *prima facie* case of obviousness. *In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002). Consequently, the Examiner's reasoning for modifying Staskin to include the missing claim limitation of claim 2 is insufficient to support a *prima facie* case of obviousness for rejecting claim 2. *Id.*

Further, the Examiner's reasoning ("in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure") does not provide reasons, as discussed further below, that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-indicated missing claim limitation of claim 2. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

Staskin addresses the problem of developing a surgical instrument suitable for incontinence procedures. [0002-0015]. The Examiner has not provided any reasons as to why one skilled in the art would modify Staskin (which addresses the problem of developing a surgical instrument suitable for incontinence procedures) to have an insertion handle comprise a digit control accommodation, the digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth (missing claim limitation). The Examiner's rationale ("in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure") does not provide such reasoning. The Examiner has not provided any evidence that by having a digital control accommodation dimensioned as set forth in claim 2 that it will provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure using the sling of the present invention of Staskin.

Hence, the Examiner's rationale does not provide reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-cited missing claim limitation of claim 2. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

- B. Claims 5 and 7 are not properly rejected under 35 U.S.C. §103(a) as being unpatentable over Staskin.

1. Claims 5 and 7 are patentable over Staskin for at least the reasons that claim 1 is not anticipated by Staskin.

Claims 5 and 7 recite the combinations of features of independent claim 1, and hence claims 5 and 7 are patentable over Staskin for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

2. Claim 5 is patentable over Staskin.

Applicant respectfully asserts that Staskin does not teach "wherein the mesh section is approximately 60 cm in length, approximately 1.5 cm to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends" as recited in claim 5. The Examiner cites paragraph [0118] of Staskin as teaching the above-cited claim limitation. Office Action (3/4/2008), page 3; Office Action (9/8/2009), page 6. Applicant respectfully traverses.

Staskin instead teaches that the associated sling 42 has a length X, width Y and thickness approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.508 mm to 0.711 mm, respectively. [0118].

Hence, Staskin teaches that sling 42 has a length within the range of 49 cm to 51 cm, a width within the range of 1.0 cm to 1.2 cm and a thickness within the range of 0.508 mm and 0.711 mm.

There is no language in the cited passage that teaches that the mesh section of the sling has a length of approximately 60 cm. Neither is there any language in the cited passage that teaches that the mesh section of the sling is approximately 1.5 cm to 3.0 cm at its widest and generally center-most position. Neither is there any language in the cited passage that teaches that the mesh section of the sling is approximately 1.0 cm wide at each of its opposite ends.

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 5, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

In response to Applicant's above arguments, the Examiner admits that the mesh section of Staskin is not approximately 60 cm in length. Office Action

(9/8/2009), page 6. The Examiner though asserts that the mesh section of Staskin could be constructed to be approximately 60 cm in length "because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Staskin's mesh and applicant's invention, to perform equally well with either the length taught by Staskin or the claimed approximate length because both would perform the same function of supporting the urethra and bladder neck ([0118] and [0119] of Staskin)." *Id.* Applicant respectfully traverses.

Staskin teaches that the associated sling 42 has a length X, width Y and thickness approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.508 mm to 0.711 mm, respectively. [0118]. Staskin further teaches that the sling is to provide the hammock support for the bladder or bladder neck. [0119].

Hence, Staskin teaches that sling 42 has a length within the range of 49 cm to 51 cm, a width within the range of 1.0 cm to 1.2 cm and a thickness within the range of 0.508 mm and 0.711 mm. Staskin further teaches that the sling is to provide the hammock support for the bladder or bladder neck.

Staskin does teach that the sling is to provide the hammock support for the bladder or bladder neck; however, there is no language in Staskin to support the Examiner's contention that the invention of Staskin supports the urethra and bladder neck as Applicant's invention and that it would perform equally well. How would it perform equally well? Where is the Examiner's proof of this statement?

Furthermore, Applicant claimed particular dimensions for various elements, such as a mesh section, of its invention for a particular purpose, namely, to claim those dimensions that allow the element to perform its function the best. There is no requirement to provide a detailed explanation in the Specification as to why each particular dimension was claimed. The Examiner appears to be trying to find an excuse to ignore claim limitations which is not permitted. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); M.P.E.P. §2143.03. Since the Examiner has not cited to any passage in Staskin as teaching the

above-cited claim limitation, the Examiner has not established a *prima facie* case of obviousness in rejecting claim 5. M.P.E.P. §2143.

Additionally, the Examiner states:

Therefore, at the time of the invention it would have been *prima facie* obvious to modify Staskin to obtain the invention as specified in claim 5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Staskin. Office Action (9/8/2009), page 6.

The Examiner has not cited to any case law or M.P.E.P. section to indicate what factors the Examiner used in concluding that having a mesh section being approximately 60 cm in length, approximately 1.5 cm to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends is merely a design choice. Based on Applicant's understanding, a "design choice," would be, for example, using a different color on a product. However, using a mesh section that is approximately 60 cm in length, approximately 1.5 cm to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends is not a similar analogy. Hence, the Examiner's assertion that using a mesh section with the above-cited dimensions is merely a design choice is incorrect.

Furthermore, the Examiner must provide a basis in fact and/or technical reasoning to support the assertion that using a mesh section with the above-cited dimensions is purely a design choice. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The Examiner must provide extrinsic evidence to support this assertion. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 5. M.P.E.P. §2112.

3. Claim 7 is patentable over Staskin.

Applicant respectfully asserts that Staskin does not teach "wherein the distal end of the sling transfer instrument is oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width" as

recited in claim 7. The Examiner cites needle 60 of Staskin as teaching the claimed curved shaft portion. Office Action (3/4/2008), pages 3-4; Office Action (9/8/2009), page 6. The Examiner further cites Figure 4 of Staskin as teaching the above-cited claim limitation. Office Action (3/4/2008), page 4; Office Action (9/8/2009), page 6. Applicant respectfully traverses.

Staskin instead teaches that Figure 4 illustrates a sling assembly 46 that includes a sling 42 for treating incontinence. [0113]. Staskin further teaches that each of the two ends 48, 50 of the elongate sling assembly 46 attaches to a first end 52 of a dilator 54 or needle-sling connector. [0115]. Further, Staskin teaches that the dilator 54 dilates a needle track for ease of sling introduction and positioning within the patient. [0115].

There is no language in the description of Figure 4 or depicted in Figure 4 of Staskin that teaches that the distal end of the sling transfer instrument (Examiner asserts that sling assembly 46 of Staskin discloses the claimed sling transfer instrument) is oriented in a direction opposite that of the progressively curved shaft portion. How is sling transfer instrument 46 oriented in a direction opposite that of needle 60 (Examiner asserts that needle 60 teaches the claimed progressively curved shaft portion)? Figure 4 does not illustrate that sling transfer instrument 46 is oriented in a direction opposite that of needle 60. Further, there is no language in the description of Figure 4 or depicted in Figure 4 of Staskin that teaches that the distal end of the sling transfer instrument (Examiner asserts that sling assembly 46 of Staskin teaches the claimed sling transfer instrument) is oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width. The Examiner has not pointed to any language in Staskin as teaching the distal end of needle 60 (Examiner asserts that needle 60 teaches the claimed progressively curved shaft portion) being approximately 1.0 cm in length and approximately 4.0 mm in width.

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 7, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

In response to Applicant's above arguments, the Examiner admits that the distal end of the sling transfer instrument of Staskin is not approximately 4.0 mm in width. Office Action (9/8/2009), page 7. The Examiner though asserts that the width of the sling transfer instrument of Staskin could be constructed to be approximately 4.0 mm in width "because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Staskin's shaft portion and applicant's invention, to perform equally well with either the width taught by Staskin or the claimed approximate 4.0 mm width because both would perform the same function of facilitating controlled passage during transvaginal deployment." *Id.* Applicant respectfully traverses.

As stated above, Staskin teaches that Figure 4 illustrates a sling assembly 46 that includes a sling 42 for treating incontinence. [0113]. Staskin further teaches that each of the two ends 48, 50 of the elongate sling assembly 46 attaches to a first end 52 of a dilator 54 or needle-sling connector. [0115]. Further, Staskin teaches that the dilator 54 dilates a needle track for ease of sling introduction and positioning within the patient. [0115].

There is no language in Staskin to support the Examiner's contention that the invention of Staskin performs the same function of facilitating controlled passage during transvaginal deployment as Applicant's invention equally well. How would it perform equally well? Where is the Examiner's proof of this statement?

Furthermore, Applicant claimed particular dimensions for various elements, such as a mesh section, of its invention for a particular purpose, namely, to claim those dimensions that allow the element to perform its function the best. There is no requirement to provide a detailed explanation in the Specification as to why each particular dimension was claimed. The Examiner appears to be trying to find an excuse to ignore claim limitations which is not permitted. All words in a claim must

be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); M.P.E.P. §2143.03. Since the Examiner has not cited to any passage in Staskin as teaching the above-cited claim limitation, the Examiner has not established a *prima facie* case of obviousness in rejecting claim 7. M.P.E.P. §2143.

Additionally, the Examiner states:

Therefore, at the time of the invention it would have been *prima facie* obvious to modify Staskin to obtain the invention as specified in claim 7 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Staskin. Office Action (9/8/2009), page 6.

The Examiner has not cited to any case law or M.P.E.P. section to indicate what factors the Examiner used in concluding that having a distal end of the sling transfer instrument be oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width is merely a design choice. Based on Applicant's understanding, a "design choice," would be, for example, using a different color on a product. However, having the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width is not a similar analogy. Hence, the Examiner's assertion that having the distal end of a progressively curved shaft portion with the above-cited dimensions is merely a design choice is incorrect.

Furthermore, the Examiner must provide a basis in fact and/or technical reasoning to support the assertion that having the distal end of a progressively curved shaft portion with the above-cited dimensions is purely a design choice. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The Examiner must provide extrinsic evidence to support this assertion. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 7. M.P.E.P. §2112.

V. ALLOWABLE SUBJECT MATTER:

The Examiner has indicated that claims 4, 18 and 19 are allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims as well as amended to be compliant with 35 U.S.C. §112, second paragraph. Office Action (9/8/2009), page 7. As indicated above, Applicant amended claim 4 to be rewritten in independent form. Accordingly, claims 4, 18 and 19 are allowable in light of Applicant's comments with respect to the rejections of claims under 35 U.S.C. §112, second paragraph.

Claim 4 was not amended to overcome prior art but to rewritten in independent form. Hence, no prosecution history estoppel arises from the amendments to claim 4. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 U.S.P.Q.2d 1705, 1711-12 (2002); 56 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2000). Further, the amendments made to claim 4 were not made for a substantial reason related to patentability and therefore no prosecution history estoppel arises from such amendments. See *Festo Corp.*, 62 U.S.P.Q.2d 1705 at 1707 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 41 U.S.P.Q.2d 1865, 1873 (1997).

VI. CONCLUSION:

As a result of the foregoing, it is asserted by Applicant that claims 1-8 and 18-19 in the Application are in condition for allowance, and Applicant respectfully requests an allowance of such claims. Applicant respectfully requests that the Examiner call Applicant's attorney at the below listed number if the Examiner believes that such a discussion would be helpful in resolving any remaining issues.

Respectfully submitted,

WINSTEAD P.C.

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